EXHIBIT C

A PILOT SAFETY, EFFICACY AND PHARMACOKINETIC STUDY OF MEDICA 16 (M16) FOR UP TO FOUR MONTHS IN OBESE, DYSLIPOPROTEINEMIC, NON-DIABETIC MALE SUBJECTS

SYNOPSIS

The safety and efficacy of Medica 16 (M16) was evaluated in 8 obese male dyslipoproteinemic subjects with treatment of up to 4 months. Enrolled subjects were placed on isocaloric diet to maintain body weight and blood lipids and placed on a 4-5 month placebo treatment study run in. The starting dose for all subjects was 200mg M16/day. One subject was maintained on 200 mg/day for three months. For the other subjects, after 2 weeks at this dose, the dose was escalated step wise up to 300 mg/day (2 subjects), 400 mg/day (2 subjects), 600 mg/day (2 subjects), and 800 mg/day (1 subject). Safety, plasma triglycerides, cholesterol and M16 concentrations were monitored through out the study.

Triglyceride levels decreased (mean 46%) within the first month of treatment in all subjects, even at the lowest dose (200 mg/day); the overall mean decrease in triglycerides was 55%.

The decline in cholesterol was 13% in the first month and approximately 16% overall.

OBJECTIVE

The objective of this pilot study was to obtain preliminary efficacy, safety and pharmacokinetic data of β,β-tetramethylhexadecanedioic acid (M16) in obese dyslipoproteinemic male volunteers.

Applicants: Jacob Bar-Tana
U.S. Serial No.: 10/735,439
Filed: December 11, 2003
Exhibit C

RESULTS

Data of individual triglyceride and cholesterol values and dose adjustments over the course of the study were obtained.

The data indicate that plasma triglycerides (TG) significantly decreased in all subjects and that the decrease was observed within the first month of treatment at even the lowest dose administered (200 mg/day). The decrease in triglycerides during the first month of treatment ranged from 27% to 65%, with an overall mean decline of 46%.

The effect on lowering cholesterol during the first month of treatment was less pronounced, ranging from approximately 4% (Subject 6) to 36% (Subject 8), with a mean decline of 13%.

An overall efficacy summary tabulated by dose is shown in Table 1. The overall mean decline was approximately 55% in triglycerides and approximately 16% in cholesterol. It is noteworthy that at 400 mg, triglycerides decreased by 70%; in three subjects. In these 3 subjects the maximum decrease in triglycerides was observed in response to 200-400 mg and reached 70%.

Along with TGs and cholesterol, HDL was also measured over the course of the study. The data indicate an increase in HDL relative to the respective basal values in 6 of the 8 subjects. The mean increase was 14% (range 8%-19%) in 5 subjects, whereas the increase was 46% in one subject. Essentially no changes from basal HDL values were found in two subjects.

TABLE 2

Summary of Efficacy

Dose (mg/day)	Treatment Duration (wks)	Parameter	Mean Decline From Basal Values (%) Subject Number								Mean ±SD
			1	2	3	4	5	6	7	8	
200	4.6±3.7	TG	32.1	64.5	18.7	30.7	47.1	53.4	30.4	65.4	43±17
	(1-12)	Ch	12.4	9.8	7.2	4.4	16.3	3.8	12.9	34.9	13±9
300	3.6±0.9	TG	21.3		58.0	43.0	71.9				48±22
	(3-5)	Ch	10.6		3.0	13.6	21.6				12±8
400	6.3±3.5	TG		67.7	52.0		75.5		40.0	72.0	61±15
	(1-10)	Ch		16.5	>8.4*		23.1		16.5	40.2	24±11
600	11	TG		70.6							70.6
		Ch		16.5							16.5
400/600	9	TG								70.0	70.0
		Ch								40.5	40.5
600/800	11	TG							39.6		39.6
		Ch							18.8		18.8
First Month		TG	27.0	34.5	33.4	38.3	57.8	48.9	30.1	64.8	46±15
		Ch	11.7	13.3	5.0	7.0	17.8	3.8	12.9	35.5	13±10

TG = triglycerides; Ch = cholesterol; ( ) = range of treatment duration

*: No used to calculate mean decline

Total number of determinations / dose group: 34 (200); 17 (300); 34 (400); 7 (600); 13 (400/600);
6 (600/800); 33 (First month)